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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PHARMACEUTICAL INNOVATIONS, INC., Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, MARGARET A. HAMBURG, COMMISSIONER OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION, and UNITED STATES OF AMERICA, Defendants.	Case No.: **COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF** **[Jury Trial Demanded]** **Filed Electronically**

INTRODUCTION

Pharmaceutical Innovations, Inc., with an address at 897 Frelinghuysen Avenue, Newark, New Jersey 07114, by and through its counsel, alleges as follows:

1. Pharmaceutical Innovations, Inc. (hereinafter "PI" or "Plaintiff") brings this action to compel Defendants United States Food and Drug Administration ("FDA"), FDA

Commissioner Margaret A. Hamburg (the "Commissioner"), and the United States of America (collectively, "Defendants" or the "Government"), to issue a Certificate of Foreign Government ("CFG") or alternative confirmation, which certain foreign governments request or require before accepting import of medical devices such as PI's ultrasound gel products.

2. The CFG is a certification process which was voluntarily initiated by the FDA decades ago to facilitate export of United States ("U.S.") manufactured devices to foreign countries because some foreign purchasers and/or governments desired confirmation from the U.S. government that such devices were lawfully marketed in the U.S. There is no statutory basis for these so called "certificates" and no promulgated rule to describe or support a lawful due process or administrative procedure for their issuance. Nevertheless, the device industry recognizes acquisition of the CFG from the FDA as a necessary custom that is helpful to the export of devices in lawful U.S. commerce.

3. For over 40 years, PI has lawfully manufactured, marketed and distributed its devices to dozens of satisfied purchasers in the United States and abroad, including foreign countries whose purchasers and governments request a CFG. Since May 8, 2012, however, the FDA has refused to issue a CFG to PI despite the fact that PI is in compliance with requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.* (the "FDCA") relating to subjective interpretations of Good Manufacturing Practice ("GMP") regulations. 21 C.F.R. Part 800. During this same time period, the FDA has not taken any action to restrain PI from the manufacture of its devices or distribution of these devices in interstate or international commerce.

4. Defendants' actions have directly harmed PI by limiting its ability to export its high-quality ultrasound gel products, cutting its international sales in half and threatening the

viability of its business. Defendants' unlawful actions are arbitrary and capricious and obviously in violation of applicable law as well as an abuse discretion for which PI's pleas of due process have been repeatedly ignored thereby confirming its compliance with a reasonable interpretation of law and regulation. PI seeks a declaratory judgment that would hold unlawful and set aside Defendants' action in denying PI the issuance of the CFG, as well as an injunction to compel the issuance of the CFG or alternative communication recognizing that PI devices are in lawful commercial distribution in the U.S.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1337, to provide remedies set forth in 5 U.S.C. § 706 and 27 U.S.C. § 2201.

6. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e) because PI's principal place of business is in New Jersey and the agency action at issue was made based upon information from the FDA's New Jersey District Office.

PARTIES

7. PI is a small entrepreneurial New Jersey corporation with its principal place of business at 897 Frelinghuysen Avenue, Newark, New Jersey 07114. PI is an industry leader in the design, development, manufacture and distribution of many medical devices, including sterile and non-sterile ultrasound accessory gels (the "Products").

8. The FDA is the federal agency authorized to administer the FDCA and related regulations, including the provisions of law at issue in this case.

9. The Commissioner of the FDA is the chief administrator of the FDA and holds the power to issue a CFG.

10. The United States of America is named as a defendant pursuant to 5 U.S.C. §§ 702 and 703, because this is an action for judicial review of agency actions that have affected Plaintiff adversely.

THE STATUTORY SCHEME

11. Pursuant to Section 201(h) of the FDCA, PI's Products are considered "devices" because, as accessories, they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

12. Under the FDCA, exportation of PI's Products is regulated under a statutory scheme that applies to devices that would violate the FDCA if distributed in domestic commerce because they are adulterated or misbranded such as "Banned" devices or devices used for investigational use. Such devices may be exported legally if FDA approves the export or if certain specific statutory requirements are satisfied. 21 U.S.C. §§ 381(e), 382.

13. However, because the FDA had no authority to recognize lawful U.S. commercial distribution to foreign purchasers or Governments and to facilitate export of devices such as those manufactured and distributed in the U.S. by PI, the FDA established an informal and voluntary program whereby it issues a non-statutory CFG confirming that the devices being exported are freely marketed in the United States. The FDA adopted this program to help, rather than harm, domestic manufacturers because foreign governments and customers are often asked to supply a verification relating to U.S. manufacture/distribution of devices subject to the FDCA.

14. Without a CFG, many foreign governments prohibit the importation of medical devices from the United States, and foreign customers will refuse to purchase such devices from United States manufacturers.

15. The FDA's decision regarding whether or not to issue a CFG directly impacts whether or not a domestic manufacturer is able to export a device that is in substantial compliance with the FDCA and related regulations and lawfully available for interstate commerce.

16. To apply for a CFG, a device manufacturer must certify to the best of its knowledge that it is operating in substantial compliance with the Good Manufacturing Practice ("GMP") regulations set forth at 21 C.F.R. pt. 820, which impose quality control requirements on device manufacturers.

17. Accordingly, when the FDA issues a CFG, it states therein that the manufacturer is operating in substantial compliance with the GMP regulations. Substantial compliance, as opposed to full compliance, is permissible, because minor and technical variances from GMP requirements are extraordinarily common and irrelevant to the public health.

FDA'S INSPECTIONS OF PI'S FACILITY

18. Invoking its authority to inspect as set forth in 21 U.S.C. § 374, the FDA conducted inspections of PI's Newark facility in or about April – May 2011, February 2012, October – November 2012 and March – April 2013. These inspections yielded a series of factual observations by subordinate FDA officials of possible GMP regulatory violations.

19. PI has submitted numerous responses to these observations and has either demonstrated that PI is in substantial compliance or adjusted its procedures to comply with a reasonable interpretation and application of GMP regulations.

20. The FDA's observations are preliminary, have not been adopted as final agency conclusions, and are subject to dispute by PI.

21. The FDA written observations and subsequent allegations of GMP violations have never been adjudicated in a judicial proceeding.

22. On July 29, 2011, the FDA issued PI a warning letter regarding certain observations from a prior inspection. PI responded fully and completely to the warning letter as well as to subsequent FDA inspectional observations and has repeatedly expressed its desire to meet with FDA officials to address the issues raised therein. Unfortunately, the FDA has not responded to numerous written communications and verbal requests to FDA representatives for a meeting.

FDA'S DECISION TO DENY PI'S APPLICATION FOR CERTIFICATE TO FOREIGN GOVERNMENT

23. On April 8, 2012, PI submitted a request to the FDA for the re-issuance of a CFG so that PI could facilitate exportation the Products internationally.

24. On May 8, 2012, the FDA informed PI that its application for a CFG had been denied. The FDA based this decision on unspecified information obtained from the FDA's New Jersey District Office. A copy of the denial of the CFG is annexed hereto as Exhibit A.

25. PI has since made repeated efforts to document explanations to the FDA and seek to understand from FDA personnel the basis for the FDA's denial.

26. The Government has indicated that the denial of the CFG was the result of certain claimed unresolved regulatory issues for which the FDA has taken no official action other than to issue the July 2011 warning letter.

27. PI is currently opposing a pending action initiated by the Government to seize a limited inventory of its Products for alleged adulteration or misbranding. It is unclear whether this seizure action is related to the FDA's denial of PI's request for a CFG.

28. With the exception of the seizure action, there have been no other federal enforcement actions against PI or any of the Products, nor has there been any basis to do so.

29. As a result of Defendants' actions in denying the CFG request, PI is unable to export its Products to foreign countries or engage in business activities with other companies who may want or require the assurance of a CFG.

30. As a result of Defendants' actions in denying PI the CFG, PI has lost approximately fifty percent (50%) of its international sales from May 2012 through 2013.

31. To date, the FDA has not restricted the manufacture or distribution of any of the Products throughout the United States or to any country or purchaser which does not require a CFG, presumably because of satisfaction with the performance of the Products which are in lawful commercial distribution in the United States.

COUNT I

(Arbitrary and Capricious Agency Action)

32. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 31 above.

33. An actual and substantial controversy exists between Plaintiff and Defendants concerning Plaintiff's satisfaction of the FDA "policy" governing issuance of a CFG.

34. The FDA's May 8, 2012 denial of Plaintiff's application for a CFG has directly injured Plaintiff by precluding it from exporting its Products to foreign customers.

35. The FDA's May 8, 2012 denial of Plaintiff's application for a CFG was an arbitrary and capricious agency action within the meaning of 5 U.S.C. § 706(2)(A), because the FDA has no such authority and PI has responded and remedied any non-compliance allegations without any acknowledgement from the FDA.

36. Furthermore, the FDA applied a different standard to Plaintiff's application than the practice applied to applications by other device manufacturers. The FDA's standard

procedure is to issue a CFG if a manufacturer does not fully comply, but does substantially comply, with the GMP regulations.

37. However, the FDA denied Plaintiff's application for a CFG notwithstanding that PI was in substantial compliance with the GMP regulations during the period when the FDA considered Plaintiff's application for a CFG.

38. The FDA's May 8, 2012 denial of Plaintiff's applications for a CFG was an arbitrary and capricious agency action, (which also was an abuse of discretion absent any due process) because the FDA based that action upon a preliminary assertion that PI did not fully comply with the GMP regulations, even though the agency has not formally and finally concluded that PI lacks full compliance with the GMP regulations.

COUNT II

(Agency Action Not in Accordance With Law)

39. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 38 above.

40. An actual and substantial controversy exists between Plaintiff and Defendants concerning Plaintiff's satisfaction of the FDA requirements governing issuance of a CFG.

41. The FDA's May 8, 2012 denial of Plaintiff's application for a CFG has directly injured Plaintiff by precluding it from exporting its Products to foreign customers.

42. The FDA's May 8, 2012 denial of Plaintiff's application for a CFG was a final agency action not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A), and a final agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right within the meaning of 5 U.S.C. § 706(2)(C), because the FDA applied an arbitrary approach to Plaintiff's application.

43. The FDA denied Plaintiff's application for a CFG notwithstanding that PI was in substantial compliance with the GMP regulations during the period when the FDA considered Plaintiff's application for a CFG.

44. The FDA's May 8, 2012 denial of Plaintiff's application for a CFG, based on alleged noncompliance with the GMP regulations, was legally erroneous and therefore was a final agency action not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A), and a final agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, within the meaning of 5 U.S.C. § 706(2)(C).

PRAYER FOR RELIEF

Plaintiffs respectfully request the Court to grant the following relief:

1. Issue a declaratory judgment declaring that:

   a. The FDA's May 8, 2012 denial of PI's application for a CFG was an arbitrary and capricious final agency action within the meaning of 5 U.S.C. § 706(2)(A); and

   b. The FDA's May 8, 2012 denial of PI's application for a CFG was a final agency action not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A), and a final agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, within the meaning of 5 U.S.C. § 706(2)(C);

2. Issue an injunction compelling the FDA to issue a CFG in response to PI's April 8, 2012 application or written confirmation of PI's lawful interstate commerce manufacture and distribution; and

3. Award such other and further relief in favor of PI as this Court deems just and proper.

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Dated: February 21, 2014

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JURY DEMAND

PI demands trial by jury of all claims and defenses in this action so triable.

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LOCAL RULE 11.2 CERTIFICATION

The matter in controversy is not the subject of any other action pending in any other court or any pending arbitration or administrative proceeding, except that the action captioned United States of America v. All Articles of Other-Sonic Generic Ultrasound Transmission Gel, Whether Labeled or Unlabeled, in any Size or Type of Container, that are Identified by Lot Number, or by other Means, as having been Manufactured by Pharmaceutical Innovations, Inc., Newark, New Jersey, between June 2011 and December 2011, and are Located anywhere on the Premises of Pharmaceutical Innovations, Inc., 897 Frelinghuysen Avenue, Newark, New Jersey 07114-2122, Civil Action No. 12-2264 (ES), involves the seizure of medical devices owned by Plaintiff.

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